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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

UNITED FOOD AND COMMERCIAL WORKERS INTERNATIONAL UNION, LOCAL 464A HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated,

Plaintiff,

v.

MERCK & CO., INC.,

Defendant.

Civil Action No.

COMPLAINT and DEMAND FOR JURY TRIAL

Plaintiff United Food And Commercial Workers International Union, Local 464A Health and Welfare Fund (the "Fund"), by way of Complaint against Defendant Merck & Co., Inc., says:

INTRODUCTION

- 1. Plaintiff Fund brings this proposed class action against Defendant Merck & Co., Inc. for its unlawful prescription co-payment ("co-pay") subsidy programs. Defendant has paid, and continues to pay, payments to health plan participants so that those health plan participants choose Defendant's branded drugs Janumet/Janumet XR/Januvia, Nasonex, Vytorin, and Zetia instead of less-expensive equivalent alternatives. In doing so, Defendant has knowingly and unlawfully subverted the intended purposes of national healthcare policy, as well as tortiously interfered with contractual relations between health benefit providers, like Allied, and their health plan participants. The end-result of Defendant's scheme is a dramatic and burdensome shift in the cost allocation for prescription medicine that injures health benefit providers, like Allied, and unjustly enriches Defendant. Indeed, because of Defendant's unlawful interference in the contractual relations between Allied and its health plan participants, Allied paid for more prescriptions of more expensive branded pharmaceuticals than it otherwise would have, while Defendant caused falsely inflated drug reimbursement rates to be reported to, and imposed on, Allied for these subsidized prescriptions.
- 2. There are numerous salutary national objectives served by the current statutory scheme governing healthcare, including increased competition within the pharmaceutical marketplace and, through vigorous competition, the availability of lower-cost prescription medicine. In providing coverage for prescription medicines, funds, like Allied, seek to take full advantage of the availability of lower-cost drug equivalents. Indeed, cost-sharing provisions in

prescription drug benefit plans unite the financial interests of the health plan with the interests of its beneficiaries. Requiring health plan participants to pay a small portion of the high cost of a branded prescription drug – either through co-pay or co-insurance – provides a reasonable, personal incentive for privately insured individuals to choose less-costly, usually generic, medications, and drives down the cost of the much larger residual portion paid by the health benefit providers.

- 3. In response to cost-sharing provisions, Defendant began subsidizing participants' co-payments for its key brand name prescription drugs. These subsidies are designed to undermine cost-sharing arrangements. By eliminating or reducing member co-pays for branded drugs, plan participants have no incentive to use less expensive generic drugs, and health benefit providers, including the Fund, end up paying for more costly branded drugs. A recent study estimated that these kickbacks will increase health benefit providers' prescription drug costs by \$32 billion over the next ten years.
- 4. Each co-pay subsidy program is one size fits all, involving a formulaic, rote discount that applies regardless of the details of the patient's cost-sharing arrangements. Participants present a co-pay subsidy card to a pharmacist. The pharmacist, in turn, uses the subsidy card or coupon as a discount on the co-pay due under the terms of the insured's respective plan, which functionally reduces out-of-pocket expense of the drug to the insured without disclosing that price reduction to the health plan. Each and every subsidy is calculated and processed electronically; the health benefit plans receive electronic records falsely indicating that the participants paid their personal cost-share obligations, yet the manufacturer's digital paper trail discloses the truth that the co-payments were subsidized by the manufacturer.

5. The Fund and the proposed Class allege that Defendant tortiously interferes with the contractual relations between the Fund and other Class members and their participants by causing the participants to breach their contractual obligations to pay co-pay amounts under the terms of their respective plans, causing the Fund and other class members to incur higher expenses for payment for Defendant's brand name drugs, rather than lower cost generic equivalents.

PARTIES

- 6. Plaintiff United Food And Commercial Workers International Union, Local 464A Health and Welfare Fund ("Fund") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. § 186, by an equal number of trustees appointed by labor representatives and union representatives. Fund is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. §186(c)(5), and is defined by Sections 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §1001, et seq. As such, Fund is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). The Fund's office is located in Little Falls, New Jersey. During the course of Defendant's subsidy schemes, Fund paid for much more expensive brand name drugs in circumstances where its participants cost-sharing obligations were not paid by them personally but were subsidized by Defendant. As a result of Defendant's illegal subsidies, Fund purchased more of Defendant's expensive brand name drugs than it otherwise would have. Fund was injured as a result of Defendant's unlawful conduct.
- 7. Defendant Merck & Co., Inc. is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Merck Drive,

Whitehouse Station, New Jersey 08889. Merck markets the branded drugs Janumet, Janumet XR, Januvia, Nasonex, Vytorin, and Zetia. From in or around 2008 through the present, Merck subsidized plan participants' co-pays in order to increase the number of Janumet, Janumet XR, Januvia, Nasonex, Vytorin, and/or Zetia prescriptions purchased by health benefit providers.

JURISDICTION AND VENUE

- 8. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332(d) in that the amount in controversy exceeds \$5 million, exclusive of interest and costs, and at least one class member is a citizen of a State other than that of Defendant.
- 9. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because Defendant resides in this District.

FACTS

- A. Branded drug manufacturers have attacked the private prescription drug copay system.
- 10. Branded drug manufacturers have attacked the private prescription drug co-pay system by subsidizing plan participants' co-pays in order to undermine cost-sharing arrangements between health benefit providers and those they insure. These co-pay subsidy programs reduce or eliminate individuals' co-pays regardless of their financial need. Co-pay subsidiary programs are, by definition, primarily or exclusively for privately insured individuals.
- 11. Whether characterized as coupons, rebates, subsidies, or kickbacks, these payments to plan participants interfere with health plans' cost-sharing provisions and intentionally influence prescription drug choices. The programs are designed specifically to reduce or eliminate privately insured individuals' personal contractual obligations so that they choose higher priced brand name drugs rather than lower priced generic equivalents, leaving their health benefit providers to foot the bill.

- 12. Although co-pay subsidy programs vary as to the drugs covered and the specific amount of the subsidy or rebate, all programs work the same way. Individuals enroll in drug-specific programs online. Individuals provide basic information (name, address, and whether they have private health plan coverage) and the drug company mails them a wallet-size card that includes instruction to pharmacists regarding how to process covered prescriptions. Some drug companies allow individuals to immediately print cards using their home computers.
- 13. Participants then present the card at the pharmacy with a prescription, and the pharmacist processes the prescription according to the instructions on the card. The pharmacist enters information into a computerized data management system in order to submit a claim, first keying in the patient's health plan information in the primary insurance field. Health plan information regarding the transaction for that particular individual and his/her health plan is transmitted back to the pharmacist from the insurance company or its pharmacy benefit manage ("PBM"), including information about the member's co-pay or co-insurance obligation. The pharmacist then enters information from the co-pay card system into the secondary insurer field Information regarding the extent of the co-pay subsidy or rebate is similarly computed, but only after the patient's primary health plan is processed (and billed).
- 14. The pharmacist and PBM use the reimbursement benchmark, which the brand name drug company provides to the reporting agency, to calculate the usual charge (i.e., unreduced by the amount of the subsidy) to the health plan for the procurement of the prescription drug. The pharmacy and PBM do so without advising the health plan that, at the same time, the plan member's personal cost share obligation is being picked up by the drug's

In the infancy of these programs, drug companies gave co-pay subsidy cards to doctors and pharmacists, who in turn gave the cards to patients. Some cards are still distributed this way, but most are now available online.

manufacturer. As a result, the private health benefit provider pays for the medication at its usual (but, in fact, now inflated) cost, and it does so without being told that the usual cost share obligation has not been paid by the enrollee, but rather by the brand manufacturer, contrary to the terms of the enrolee's particular health plan.

- 15. In effect, Defendant bribes plan participants to choose its branded drugs over less-expensive therapeutic alternatives in order to get the health benefit plan to pay for the bulk of the cost of its more expensive branded drugs. From the member's perspective, the branded drug and therapeutic alternatives cost close to, if not exactly, the same amount. However, the price of the health benefit plan's share of the therapeutic alternative with the lower co-pay and the branded drug with the higher co-pay may differ by a factor of ten.
- 16. By way of example, a brand drug company offers a co-pay card giving privately insured individuals the opportunity to save up to \$25 off their cost share for each prescription filled for a particular, and expensive, medication for chronic illness. The plan member brings the co-pay card to his pharmacy and provides his insurance card and co-pay card to the pharmacist. The pharmacist processes information from the insurance card and transmits it to the PBM. The PBM recognizes the drug as a TIER 3 brand drug for the plan member, and relays a \$70 obligation to the health plan and a \$30 co-pay obligation to the plan member. In a separate transaction, the pharmacist processes information from the co-pay savings card or coupon. The co-pay card program administrator recognizes the \$30 co-pay and covers \$25 thereof, leaving \$5 for the plan member to pay out-of-pocket (while the pharmacy charges the remaining \$25 to the manufacturer through the co-pay card program administrator). The health plan is required to pay for the branded drug as if it were priced at \$100, even though the usual cost for these subsidized

transactions is \$75, and even though there are equally appropriate, less expensive medications available at prices around 1/3 the cost of the branded drug.

- 17. By their terms, Merck's co-pay subsidy programs (i) apply to individuals who are privately covered under a prescription drug plan that requires personal cost sharing by the member for retail prescription drugs such as those covered by the co-pay subsidy programs; (ii) undermine the contractual arrangement between the health plan and the health plan's member by reducing or eliminating the personal cost-share obligations under the health plan contract; (iii) cause the health benefit provider to pay for more units of expensive co-pay subsidy drugs than it would have if the Defendant had not interfered with the parties' performance of the contract, and (iv) increase the overall burden on the plan for providing benefits to its participants.
- 18. Co-pay subsidy programs are also effectively a form of secondary insurance, whereby Defendant agrees to cover a portion of the privately covered individual's prescription drug expenses. Prescription drug benefit plans, along with the formularies under which they operate, set forth appropriate balances in coverage terms, means of access, payment obligations and cost-sharing provisions for medications. Prescription drug plan contracts, whether they are wholly private plans or plans that are privately administered but publicly subsidized (such as Medicare Part D plans or managed Medicaid drug plans), are governed by myriad federal and state laws and regulations which ensure that the plans properly balance the availability of prescription drugs and sensible financial terms. Defendant's co-pay subsidies, however, function as unregulated secondary health insurance that, after payment by the primary health plan, swoop in to relieve the plan member of specifically designed personal financial obligations. By doing so, the co-pay subsidy programs fundamentally change the nature of the regulated relationship between health plan and its participants. Although Defendant's co-pay subsidies function as a

form of secondary insurance, Defendant does not comply with the myriad laws governing the provision of health insurance.

- B. Cost sharing is critical to the effective functioning of health care in the United States.
- 19. In most economic systems, the person who selects the product or service is also the person who pays for the product or service. Health care is a notable exception. Typically, a physician or other health care provider (in consultation with the patient) chooses the medication or medical procedure, the patient receives the care or consumes the medication, and public or private health benefit provider pays for the services and medication. The payer is separated from those who make the purchasing decision. Without cost-sharing provisions, such as percentage co-insurance or graduated co-pays, those choosing the prescription drugs (the patients in consultation with their physicians) have little or no incentive to choose less costly drugs.
- 20. Public and private health plans rely on cost sharing to re-align the interests of patients, health care providers, and health benefit providers. Although cost-sharing technique vary by type and amount, they all have the singular purpose of imposing a personal financial obligation on the covered individual in order to encourage price sensitivity and achieve the rang of acceptable balance between coverage and cost. Individuals with health plans often face point-of-service charges for medical services and prescription drugs. These include deductibles (amounts that must be paid before some or all services are covered), co-payments (fixed dollar amounts), and/or co-insurance (a percentage of the charge for services). Health benefit providers impose different degrees of cost sharing for different services: annual deductibles for medical services, separate deductible for prescription drugs, hospital and outpatient co-insurance, co-pays for physician office visits, and/or out-of-pocket maximum amounts.

- 21. Cost sharing is therefore fundamental to almost all medical spending in the United States. Whether it be for hospital, physician, dental, or other health care provider services, for employer-sponsored or individual plans, for medical procedures, or for prescription drugs, numerous forms of cost sharing are imposed as a critical component of public and private health plans in order to carefully incentivize cost-conscious use of medical services and products while at the same time affording appropriate access to medical care.
 - C. The routine waiver of cost-sharing obligations, including co-payments and co-insurance, for medical services and products is unlawful.
- 22. Recognizing the ubiquity and necessity of cost sharing, federal and state statutes declare the practice of routinely waiving co-payment obligations for medical services and products to be unlawful.
- 23. First, routinely waiving co-pays constitutes financial inducements that are deemed illegal kickbacks. The waiver is in effect a form of payment that induces the use of medical services or products offered by the party that routinely waives co-pays. The routine waiver of co-pays amounts to health care fraud and is criminal.²
- 24. In the public arena, physicians, hospitals, and medical products providers who receive payment through Medicare or Medicaid programs and routinely waive co-payments or deductibles may be held in violation of federal and state anti-kickback statutes. The federal anti-

¹⁸ U.S.C. § 1347 Health care fraud ("Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services, shat be fined under this title or imprisoned not more than 10 years, or both. . . [A] person need not have actual knowledge of this section or specific intent to commit a violation of this section."); 18 U.S.C. § 1349: Attempt and conspiracy ("Any person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those prescribed for the offense").

kickback statute prohibits the payment of remuneration (any kickback, bribe or rebate) when it is knowingly paid to induce business that will be paid for by a federal health care program.³ Further, the routine waiver of co-payments in the Medicare and Medicaid areas forms the basis for a violation of the False Claims Act and the Civil Monetary Penalties Law.⁴

25. The terms of Merck's co-pay subsidy also violate federal and state anti-kickback statutes. The federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)(2)) provides:

Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly . . . to any person to induce such person . . . to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

26. The Massachusetts False Health Care Claims Act (MASS. GEN. LAWS ch. 175H, 3) similarly provides:

[A]ny person who offers or pays any remuneration, including any bribe or rebate, directly or indirectly . . . to induce any person to purchase . . . any good, facility, service, or item for which payment is or may be made in whole or in part by a health care insurer, shall be punished by a fine of not more than ten thousand dollars, or by imprisonment in a jail or house of correction for not more than two and one-half years or in the state prison for not more than five years, or by both such fine and imprisonment, and may be held liable in a civil action.

27. Defendant knowingly offers and pays remuneration in the form of co-pay subsidies to patients in order to induce them to purchase Defendant's brand name drugs. The federal government has acknowledged that co-pay subsidy programs may well violate the federal anti-kickback statute.⁵

⁴ See 42 U.S.C. §1320a-7a; 31 U.S.C. § 3729.

³ 42 U.S.C. § 1320a-7b(b).

⁵ See Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees 70 Fed. Reg. 70623, 70624 (Nov. 22, 2005) ("[W]e conclude that

- 28. Merck knows that subsidizing a co-payment for a drug paid for by the federal government or a Massachusetts resident would violate the statutes and, thus, Merck attempts to exclude the use of its co-payment subsidy programs by those persons
- 29. Massachusetts is the only state that statutorily bans co-pay coupons for private payers. Were it to repeal that law, a recent study suggests that prescription drug costs for employers and other plan sponsors in Massachusetts would increase by \$750 million by 2021. Many states that do not explicitly prohibit these programs will see similar or even larger increases. For example, Illinois plans are expected to spend nearly \$1.4 billion extra on prescription drug costs as a result of co-pay coupons or programs during that time; Florida, New York, California and Texas will spend an extra \$2 billion each in the next decade as a result of the same programs.⁶
 - D. Health benefit providers use cost sharing to cope with ever-increasing prescription drug costs.
- 30. Cost sharing has particular importance in the coverage for prescription drug benefits. In 2000, prescription drug spending in the U.S. exceeded \$142 billion. By 2009, spending ballooned to more than \$300 billion. This increase in drug spending is in large part due to high and rising prices for the most well-known and most often used brand name drugs. In recent years, the price of the most widely used brand name drugs increased annually at

pharmaceutical manufacturer PAPs [Patient Assistance Programs] that subsidize Part D cost-sharing amounts present heightened risks under the antikickback statute.").

Visante, "How Copay Coupons Could Raise Prescription Drug Costs By \$32 Billion Over the Next Decade", No-2011, available at http://www.pcmanet.org/images/stories/uploads/2011/Nov'2011/visante% 20copay% 20coupon% 20study.pdf ("Visante Study"), at 13-15.

approximately 6% to 9% — two or three times the general rate of inflation. Each of the drugs a issue in this action has seen significant price increases in recent years.

- 1. Public and private health benefit providers use tiered cost sharing to reduce spending on prescription drugs.
- 31. For both public and private health benefit providers, prescription drug cost sharing is widely and effectively used, and has been for many years.
- 32. In the public realm, beneficiaries under Medicaid have, for years, been required to pay a portion of the cost of their medications despite the fact that Medicaid eligibility is limited to low-income and disabled individuals. Similarly, even beneficiaries under Medicare Part B generally the elderly receiving critical physician or in-home services have been required to share the costs of their medications. More recently, beneficiaries under Medicare Part D are required to make co-payment or co-insurance payments under terms specified by Medicare Part D plan sponsors.
- 33. Most health insurance in the United States is provided by private health benefit providers. In the private realm, cost sharing for prescription drugs is similarly widespread. Under private health benefit plans, individuals and employers pay premiums to health benefit providers and, in turn, the health benefit providers agree to pay all or a portion of the cost of needed medical services and products. Well over 95% of covered employees in employer-sponsored private health benefit plans have prescription drug benefits. More often than not, the form of cost sharing is a co-payment rather than co-insurance, although co-insurance has steadily increased over time.

In the United States, most private health insurance is paid at least in part by employers, although it is also common for employees to contribute to the cost of their premiums. Truly individual health insurance policies may also be purchased.

- 34. Drug benefit cost-sharing provisions have evolved over the decades, with the key innovation being the differentiation of co-payments among differing drugs. When drug insurance was first introduced, the plan member typically paid the same co-insurance (or co-pay), rate for any drug. Over time, that changed, and the price now depends on the "tier" in which the drug is placed. The early tiered plans typically had only two tiers, but most plans now have three or more tiers. In recent years, an increasing number of plans have created a fourth tier of drug cost sharing, which may be used for lifestyle drugs or expensive biologics:
- 35. The number of plans requiring some form of cost sharing that differentiates between forms of drugs has steadily increased, but has plateaued in recent years. Almost 90% of privately covered individuals have some formula for tiered cost sharing: over 75% are enrolled in plans with three, four, or more tiers of cost sharing for prescription drugs.

Generic drugs: A drug product that is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.

Preferred drugs: Drugs included on a formulary or preferred drug list; for example, a brand name drug without a generic substitute.

Non-preferred drugs: Drugs not included on a formulary or preferred drug list; for example, a brand name drug with a generic substitute.

Fourth-tier drugs: New types of cost-sharing arrangements that typically build additional layers of higher co-payments or co-insurance for specifically identified types of drugs, such as lifestyle drugs or biologics.

Brand name drugs: Generally, a drug product that is covered by a patent and is thus manufactured and sold exclusively by one firm. Crosslicensing occasionally occurs, which allows an additional firm to market the drug. After the patent expires, multiple firms can produce the drug product, but the brand name or trademark remains with the original manufacturer's product.

36. A drug's tier placement largely depends on its cost: Tier 1 drugs are less expensive, usually generic, drugs. More expensive, usually brand name, drugs are placed on

higher tiers. Health benefit providers encourage participants to choose Tier 1 drugs by imposing a lesser co-pay than that imposed for Tier 2 drugs. Tiered co-payments and co-insurance (which a percentage of the overall cost of the drug at retail rather than a flat amount) thereby provide reasonable personal financial incentives to individuals to use equally effective, but less costly, medications. If a drug is placed on Tier 1, the member pays the pharmacy a relatively small co-payment. If the drug is placed on Tier 2, the co-payment or co-insurance obligation increases. The difference in the co-payment/co-insurance between Tier 2 and Tier 1 incentivizes the plan member to choose the less costly medication. If a drug is a Tier 3 drug, a therapeutic or generic equivalent will invariably exist for the medication in Tier 2 and/or Tier 1.

- 37. Another major, long-term trend has been the increasing amount of the co-payment or co-insurance required. Over the last decade, average retail co-payment levels increased by about 62%. Average co-payments for Tier 2 drugs increased by about 127%. Average co-payments for Tier 3 drugs increased the most, from about \$17.53 in 1998 to about \$42.95 in 2009, an increase of about 149%. As expected, the 2009 average retail co-payment for Tier 4 drugs is even greater, at \$62.11.
- 38. Widespread use of cost sharing for prescription drugs, the increasing trend of multi-tier cost sharing and the increasing amounts for co-payments and co-insurance are, of course, no accident. Although other forms of prescription drug cost reductions may have more dramatic results, including the market entry of AB-rated generic equivalents, cost sharing has defined, measurable results. Cost sharing provides personal financial incentives to plan participants to select the most cost-appropriate medications; these incentives work.
- 39. Patients, and to a lesser extent, their doctors, are sensitive to differences in copayment requirements, particularly for maintenance drugs that they anticipate taking for long or

indefinite periods of time. According to a 2007 literature review published in the Journal of the American Medical Association, every 10% increase in cost sharing (through co payments o coinsurance) reduces drug spending by 2 - 6%. Drug companies are well aware that plan participants consider co-pay differences when choosing prescription drugs: "[t]he patient, I will to you, is economically very, very sensitive to co-pays, and a \$5, \$10, \$20, \$25 co-pay matters," according to Abbott Laboratories Chief Executive Miles White.⁸

- 2. Branded drugs are expensive; differentiated cost sharing for branded and generic drugs help health benefit providers and health plan participants curtail prescription drug spending.
- 40. Generic drugs thus play a critical role in health benefit providers' attempts to curb ever-escalating prescription drug costs. Generic drugs are almost always significantly less expensive than their branded counterparts. On average, generic prescriptions cost payers \$16, preferred brand prescriptions cost \$118, and non-preferred brands cost \$124. Tiered cost-sharing provisions thus incentivize generics by imposing a lower co-pay or co-insurance for generics than for brands.
- All fifty states have laws that permit pharmacies to substitute AB-rated generics for their brand counterparts when an AB-rated equivalent is available. Health benefit providers create strong incentives for plan participants to demand generic drugs by imposing different co-pays for brander and generic drugs. Consequently, more than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. 2010 IMS industry data,

⁸ Event Brief of Q2 2009 Abbott Earnings Conference Call —FD (Fair Disclosure) Wire (July 15, 2009).

the industry's gold standard, reflects that, on average, AB-rated generics capture 80% of the brand's sales within the first six months of the generic being available for sale.

42. In addition to AB-rated generics, a brand-name drug may also have generic therapeutic alternatives. Therapeutic alternatives are not bioequivalent to their brand-name counterparts, but are alternative medicines that treat the same medical condition in a similar way. As an example, Pfizer's blockbuster drug Lipitor belongs to a therapeutic class of drugs called "statins" used to treat high cholesterol, but because statins work in similar ways, a patient and/or physician may determine that another statin, such as generic simvastatin, lovastatin, and pravastatin, is a sensible cost-effective alternative, particularly since (without a co-pay subsidy) the cost to the patient by reason of the tiered co-payment system would be much higher for Lipitor than for a generic statin.

- E. Co-pay subsidies work: health plan participants fill prescriptions for branded drugs instead of generics and health benefit providers pay much higher prices for the subsidized prescriptions.
- Association and based on evidence from drug coupon administrators, "25% of [co-pay] coupon use results in a couponed drug being used instead of a preferred brand or generic that might have been used in the absence of the coupon." More than 100 million prescriptions were associated with co-pay coupons in 2010, accounting for 11% of brand prescriptions. These numbers will grow exponentially: at current trends, the number of prescriptions associated with co-pay subsidy programs will increase by 15% per year, reaching 500 million prescriptions and approximately

⁹ Visante Study at 11.

¹⁰ *Id.* at 12.

50% of non-specialty brand prescriptions by 2021.¹¹ All told, employers and other plan sponsors will likely spend an extra \$32 billion on prescription drugs as a result of these co-pay subsidy programs over the next decade.¹²

- 44. It is estimated that pharmaceutical companies spend \$4 billion on co-pay cards and coupons annually. Drug manufacturer Amgen has stated publicly that spending on its co-pay subsidy programs amounts to about 1% of its total product sales. In the first quarter of 2010, Amgen spent \$35 million on co-pay subsidy programs. This amount is likely to increase as more co-pay programs are created and more plan participants take advantage of existing programs.
- 45. Brand-name pharmaceutical manufacturers know that these co-pay subsidy programs work. These programs are now a regular part of life cycle planning for branded drugs, typically launching two to three years before AB-rated generic equivalents of the brand name drug are expected to enter the market. The manufacturer tries to maximize the number of prescriptions written by physicians, filled by participants, and paid for by both participants and health benefit providers before pharmacies begin automatically substituting the AB-rated generic equivalents for the brand name drug.
- 46. Health benefit providers have seen significant increases in the number of prescriptions filled for brand name drugs that have co-pay subsidy programs. Recently, co-pay

¹¹ *Id*.

Id. at 3, 13-15.

Matthew Herper, *How Bargain Lipitor Could Raise Health Costs*, FORBES.COM, http://blogs.forbes.com/matthewwherper/2001/03/16/how-bargain-lipitor-could-raise-health-costs/(last visited Mar. 2, 2012) (citing Mason Tenaglia, managing director of the Amundsen Group, a consulting firm that has studied the cards). *See* also Visant Study at 6.

subsidy administrators have anecdotally reported that their unnamed clients, manufacturers of branded drugs, earn between a 4:1 and 6:1 return on their investments in these programs.

- 47. The attack on prescription drug co-payment system is open and notorious. Large branded drug companies reflexively subsidize co-payments for many brand name drugs simply because they are nearing patent expiry. Co-payment subsidy administration has become a cottage industry. Program administrators boast about the effective and efficient methods by which they have wiped out the personal financial incentives of plan enrollees to select, in consultation with their physicians, less costly medications.
- 48. Drug companies, including Defendant, not only determine the price at which wholesalers or large retailers will purchase prescription drugs from them, but also control the reimbursement benchmark used to determine the amount to be paid for the drugs by public and private health benefit providers. Either by directly determining the so-called average wholesale price (or "AWP") or by determining a related price benchmark known as the wholesale acquisition price (or "WAC") that reporting agencies use to mathematically determine the AWP, branded drug manufacturers cause to be published the widely-used and nearly ubiquitous benchmark prices for payments and reimbursements that health benefit providers make to pharmacies for branded, retail-channel drug products.
- 49. Branded drug manufacturers, including Defendant, know that the reported benchmark that they control is required to be a reasonably fair estimation of the actual price for the ingredient cost of the drug to the retailer. When a prescription for a privately covered individual is filled at the retail level (*i.e.*, a pharmacy), the pharmacy charges the member's plan for the ingredient cost of the drug plus a dispensing fee. The amount to be charged for the ingredient cost is based on a percentage discount from the benchmark (*e.g.*, AWP minus 14% for

all branded drugs). Thus, the stated benchmark represents the price that all participants – the health benefit provider, its pharmacy benefit manager, the pharmacy and the manufacturer – understand is a reasonable estimate of the actual cost to the pharmacy on which the payer's reimbursement to the pharmacy is based. If a cost-sharing provision exists for the member's prescription drug plan, then the cost share (e.g., co-payment or co-insurance) is deducted from the amount owed by the plan to the pharmacy and is imposed on the member as payment to the pharmacy. However, for subsidized co-pays, the true benchmark is less, resulting in an inflated payments by the health plan.

- F. Defendant Merck subsidized consumers' co-pays for Janumet/Janumet XR/Januvia, Nasonex, Vytorin, and Zetia.
- 50. Defendant designed and implemented the programs described below (collectively referred to as the "co-pay subsidy programs"), relating to the brand name drugs Janumet/Janume XR/Januvia, Nasonex, Vytorin, and Zetia (collectively, the "co-pay subsidy drugs").
- 51. Each of Defendant's co-pay subsidy programs described below alters the carefully calibrated co-payment system negotiated by health benefit providers and their participants. Each is intended to steer unsuspecting participants toward more expensive brand name drugs when less expensive therapeutic alternatives are available in generic form, with generic price tags.
 - 1. Merck's Multi-Use Savings Card for Januvia, Janumet, and Janumet XR
 - a. Merck faced competition from less expensive alternatives to Januvia and Janumet.
- 52. On October 16, 2006, the FDA approved Januvia (sitagliptin phosphate) to improve glycemic control in patients with type 2 diabetes.
- 53. On March 30, 2007, the FDA also approved Janumet (metformin hydrochloride and sitagliptin phosphate) to improve glycemic control in patients with type 2 diabetes who are

not adequately controlled by metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metfon-nin. Thus, Janumet is combination of Januvia (sitagliptin) and metformin.

54. Near the end of 2010, Dick Clark, Merck's President and CEO, told investors that it was offering a coupon to offset patient co-pays for Januvia as a way of helping the company "attack the market that is being held now by . . . generic[] sulphonylureas."

DAVE RISINGER [ANALYST, MORGAN STANLEY]: That is great. One thing that some brand companies are using • . . to drive consumer demand is buying down co-pays and offering more co-pay assistance. Is that something that Merck is developing as well?

DICK CLARK [CHAIRMAN, PRESIDENT & CEO, MERCK & CO., INC]: Well, we are very committed to making sure that our products are in a competitive situation in any plan that they are represented in. So . . . we actually try to deal with whatever barriers might be there to using our products. So for example couponing around Januvia is an example of ways of helping people to deal with co-pays and helping us to attack the market that is being held now by . . generic[] sulphonylureas. 14

- 55. In 2010, U.S. sales of Janumet exceeded \$459 million. U.S. sales of Januvia were over \$1 billion.
- 56. Less expensive therapeutic alternatives to Janumet and Januvia include metformin, meglitinides, glipizide, and sulfonylureas.

Merck & Co., Inc. at Morgan Stanley Global Healthcare Conference – Final, FD (Fair Disclosure) Wire (Sept. 13, 2010).

- b. In the wake of substitution competition from less expensive therapeutic alternatives, Merck created the Multi-Use Savings Card for Janumet and Januvia.
- 57. To combat the substitution competition it was facing from less expensive therapeutic alternatives, in or around 2010, Merck created the Multi-Use Savings Card¹⁵ for Jantunet and Januvia:



► Free Trial Offer for JANUVIA

Certain restrictions apply. Please see Terms and Conditions.

▼ Pay As Little As \$5 Certain restrictions apply. Please

see Terms and Conditions

► Sign Up for Free Support

Steps to Balance can help you learn more about living with type 2 diabetes.

Eligible patients may

Pay as little as \$5 on each of up to 12 qualifying prescriptions.

Maximum savings is \$100 per prescription.

If you are eligible, follow these steps to pay as little as \$5 on each of up to a total

of 12 qualifying prescriptions:

- Activate and print the Multi-Use Savings Card and take it to your doctor.
- If your doctor thinks that the product is the appropriate treatment for you, he or she will write a prescription.
- Take the prescription and the Multi-Use Savings Card to a participating eligible retail or mail-order pharmacy (certain restrictions apply).

The card is not insurance. Not all patients are eligible.

Merck also refers to its Multi-Use Savings Card as a Multi-Use Savings Coupon.

The card is valid for patients with private insurance or cash-paying patients. Not valid for patients covered under Medicaid, Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program.

The card is void for Massachusetts residents if a third-party payer reimburses or pays any amount of the prescription price or otherwise provides coverage for the purchased product.

The card can be used only by eligible United States or Commonwealth of Puerto Rico residents at participating eligible retail or mail-order pharmacies in the United States or the Commonwealth of Puerto Rico. Product must originate in the United States or the Commonwealth of Puerto Rico.

Please see full Terms and Conditions on the card.

Please note: The same card offer is available in different forms. For example, you may receive the card from your doctor, or you may print the card yourself from the product Web site. Regardless of how many cards you receive or print, you may only use the cards, and save on co-pay or out-of-pocket costs over \$5 up to a maximum of \$100 off a qualifying prescription, a total of 12 times before the expiration date printed on the cards.

- 58. On February 2, 2012, the FDA approved Janumet XR (metformin hydrochloride and sitagliptin extended-release), to improve glycemic control in patients with Type 2 diabetes when treatment with both sitagliptin and metformin extended-release is appropriate. The Multi Use Savings Card can now also be used with Janumet XR.
- 59. The Multi-Use Savings Card allows eligible patients to pay as little as \$5 per prescription on up to twelve qualifying prescriptions of Janumet, Janumet XR, or Januvia, with maximum savings of \$100 per prescription. The offer, which at one point was set to expire December 31, 2012, ¹⁶ is now set to expire December 31, 2013. ¹⁷

An earlier version of the Multi-Use Savings Card applied only to Janumet and Januvia.

In addition, patients can receive a free thirty-day trial supply of Janumet through December 31, 2012. no personal information is necessary to print the free trial offer online.

60. Patients can obtain a Multi-Use Savings Card from their doctor or print one directly from the website:



- 61. The Multi-Use Savings Card is not a need-based program. It is open to all patients with a prescription for Janumet, Janumet XR, or Januvia, and it subsidizes the co-pays of any privately covered patients. Patients must simply agree to certain terms and conditions and enter an email address, name, and address. They may then print the coupon directly from Merck's website: https://www.activatethecard.com/6231/welcome.html?src=JMO6R.
 - c. The Multi-Use Savings Card specifically provides that it does not apply to Medicare and Medicaid patients or to residents of Massachusetts.
- 62. Merck's website outlines the Terms and Conditions governing the Multi-Use Savings Card for Janumet, Janumet XR, and Januvia. As is noted in Paragraph 57 above, the Terms and Conditions expressly exclude Medicare and Medicaid patients and certain residents of Massachusetts.
- 63. When patients activate new savings coupons through www.januvia.com, they are asked, prior to inputting any other identifying information, in which state they reside. If Massachusetts is selected, the patient is prompted to answer. "Does a third-party payor reimburse or pay any amount of the prescription price or otherwise provide coverage for JANUMET XR, JANUMET, or JANUVIA?" Should the patient answer "yes," a pop-up window appears that says: "The Multi-Use Savings Coupon is not valid for residents of Massachusetts if a third-part) payer reimburses or pays any amount of the prescription price or

otherwise provides coverage for JANUMET XR, JANUMET, or JANUVIA. You are not eligible to participate in the Multi-Use Savings Coupon Program for JANUMET XR, JANUMET, or JANUVIA."

- d. The Multi-Use Savings Card functions as an unlawful form of secondary health insurance.
- 64. The fine print accompanying the Multi-Use Savings Coupon states: "This card is not insurance." The very same fine print, however, instructs pharmacists to process the coupon just like any other form of secondary health insurance coverage:
 - Submit transaction to McKesson Corporation using BIN No. 610524.
 - If primary coverage exists, input card information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response. For cash-paying patients, Pharmacist agrees to charge not more than the usual and customary retail price.
- 65. Despite Merck's disclaimer, the Multi-Use Savings Coupon functions and is processed as secondary health insurance.
 - e. Merck knows that third party payors cannot tell when a co-pay is subsidized.
- 66. Merck knows that the Janumet, Janumet XR, and Januvia co-pay subsidy program that Merck and its co-pay savings card administrator have designed makes it impossible for third-party payors to tell if their participants' co-pays are being subsidized by co-pay coupons. Merck admits as much in the fine print that accompanies the savings card, where it attempts to push onto the patient the responsibility for making such disclosures: "Patient is responsible for reporting receipt of card benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the card, as may be required." By burying a disclosure like this in a sea of fine print, Merck makes a weak attempt to shield itself from liability with instructions it knows and intends will not be seen or followed.

2. Merck's Nasonex Savings Coupon

- a. Merck faced competition from less expensive therapeutic alternative; to Nasonex.
- 67. On October 1, 1997, the FDA approved Nasonex (mometasone furoate monohydrate) for the prevention and treatment of seasonal nasal allergies in adults and children twelve years of age and older. Nasonex was subsequently approved for the treatment of nasal polyps in certain patients.
- 68. At the end of 2004, the drug's manufacturer, Schering-Plough (Schering-Plough merged with Merck in 2009), embarked on a new direct-to-consumer (DTC) campaign to increase sales of Nasonex.¹⁸ By mid-2006, the company bragged to investors that it had "transformed this 8-year-old product into the fastest-growing brand in the nasal inhaled steroid category," with sales growing by 25% in the first quarter of that year.¹⁹ By 2008, Schering-Plough's Chairman and CEO, Fred Hassan, reassured investors that Nasonex had done well, despite "all the competition that ha[d] come on the market."²⁰ It was clear, however, that sales of Nasonex in the U.S. were down.²¹

Event Brief of Q4 2004 Schering-Plough Earnings Conference Call – Final, FD (Fair Disclosure) Wire (Jan. 25, 2005).

Schering-Plough at Goldman Sachs Annual Global Healthcare Conference – Final, FD (Fair Disclosure) Wire (June 15, 2006).

Schering-Plough Launches Productivity Transformation Program To Confront New Challenges – Final, FD (Fair Disclosure) Wire (April 2, 2008).

²¹ Q1 2008 Schering-Plough Earnings Conference Call – Final, FD (Fair Disclosure) Wire (April 23, 2008).

- 69. AB-rated equivalents to Nasonex will not be available until at least 2018. Less expensive therapeutic alternatives to Nasonex include fluticasone propionate (Flonase) and other prescription allergy medications.
 - 70. In 2010, U.S. sales of Nasonex exceeded \$886 million.
 - b. In the wake of substitution competition from less expensive therapeutic alternatives, Merck (then Schering-Plough) created the Nasonex Savings Program.
- 71. To combat the substitution competition it was facing from less expensive therapeutic alternatives, in or around 2008, Schering-Plough (Merck merged with Schering-Plough in 2009) created the Nasonex Savings Program:
- 72. In or around 2011, Merck's Nasonex Savings Program offered a single-use coupon for up to \$15 off a patient's monthly co-pay. A patient was limited to using one coupon every thirty days. The offer was set to expire June 30, 2012.
- 73. The Nasonex Savings Program was advertised directly to individuals through full color advertisements in magazines. One print advertisement, for example, advised parents of the potential savings through the Nasonex Savings Program: "Save up to \$120 on refills a year + 1 FREE 30-day supply (equals) 2 great reasons to sign up today at nasonexparents.com. Join the Nasonex Personalized Savings Program today!"
- 74. Merck presently advertises and offers a Multi-Use Savings Coupon, with which eligible patients may receive up to \$15 off of their co-payments for each of up to six qualifying prescriptions. This coupon is set to expire June 30, 2013.

For adults and children aged 2 years and older, once-daily NASONEX is clinically proven to help relieve both seasonal (outdoor) and year-round (indoor) nasal allergy symptoms including congestion, sneezing, itchy nose or runny nose. It is important that you take NASONEX regularly as recommended by your doctor, since its effectiveness depends on regular use. Maximum treatment benefit is usually achieved in 1 to 2 weeks.

Important Safety Information

- Infections of the nose and throat may occur.
- NASONEX may cause slow wound healing. Do not use NASONEX until your nose is healed if you have a sore in your nose, if you have surgery on your nose or if your nose has been injured. Important Safety Information continued below

Special Offers for Eligible Patients:

Print a Multi-Use Savings Coupon for NASONEX

PRINT COUPON NOW

Please see Terms and Conditions

Eligible patients may save up to \$15 off on each of up to 6 qualifying prescriptions of NASONEX.

NASONEX is a prescription medicine. Only your health care provider can decide if NASONEX is right for you.

The Multi-Use Savings Coupon can be used up to 6 times before the expiration date and provides a maximum benefit of up to \$15 off the amount of your out-of-pocket costs, whichever is less, on each of up to 6 qualifying prescriptions.

To receive up to \$15 in savings on your out-of-pocket cost for NASONEX.

- 1. Print the Multi-Use Savings Coupon.
- **2.** Present the coupon and your insurance card (if any) with a valid signed prescription at any participating eligible retail or mail-order pharmacy (certain restrictions apply).

The coupon is not insurance.

Eligibility Restrictions Apply.

The coupon is valid for patients with private insurance or cash-paying patients. Not valid for patients covered under Medicaid, Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program.

The coupon is void for Massachusetts residents if a third-party payer reimburses or pays any amount of the prescription price or otherwise provides coverage for NASONEX.

The coupon can be used only by eligible US or Commonwealth of Puerto Rico residents at any participating eligible retail or mail-order pharmacy in the United States or the Commonwealth of Puerto Rico. Product must originate in the United States or the Commonwealth of Puerto Rico.

This offer is subject to certain terms and conditions. See full terms and conditions on coupon.

Terms and Conditions

- This coupon is valid for up to \$15 off on each of up to 6 qualifying prescriptions for NASONEX.
- Limit 1 coupon per patient for the duration of the program.
- Coupon is valid for use 6 times only. Patient must have a copayment or make full
 cash payment for the prescription. Savings are limited to amount of your out-ofpocket cost, up to a maximum of \$15 per prescription for up to 6 qualifying
 prescriptions.
- No other purchase is necessary.
- This coupon is not transferable. No substitutions are permitted. Cannot be combined with any other coupon, free trial, discount, prescription savings card, or other offer.
- This coupon is not insurance.
- This coupon is valid for patients with private insurance or cash-paying patients.
 Not valid for patients covered under Medicaid, Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program.
- This coupon is void for Massachusetts residents if a third-party payer reimburses or pays any amount of the prescription price or otherwise provides coverage for NASONEX.
- You must be 18 years of age or older to redeem this coupon for yourself or minor. Patient, guardian, pharmacist, and prescriber agree not to seek reimbursement for all or any part of the benefit received by the recipient through this offer. Patient or guardian is responsible for reporting receipt of coupon benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using this coupon, as may be required.
- This coupon can be used only by eligible United States or Commonwealth of Puerto Rico residents at participating eligible retail or mail-order pharmacies in

the United States or the Commonwealth of Puerto Rico. Product must originate in the United States or the Commonwealth of Puerto Rico.

- This coupon is the property of Merck and must be turned in on request.
- It is illegal to sell, purchase, trade, or counterfeit, or offer to sell, purchase, trade, or counterfeit the coupon. Void if reproduced where prohibited by law, taxed, or restricted.
- Merck reserves the right to rescind, revoke, or amend this offer at any time without notice.
- Expiration Date: 06/30/2012.

Please Note: The same coupon offer is available in different forms. For example, you may also receive the coupon from your doctor. Regardless of how many coupons you receive or print, you may only use the coupons and receive up to \$15 off an eligible prescription, up to 6 times before the expiration date printed on the coupon.

- 75. The Nasonex Coupon is not a need-based program. It is open to all patients with a prescription for Nasonex, and it subsidizes the co-pays of any privately covered patients. Patients can print the Multi-Use Savings Coupon from Merck's website²² without providing any identifying information.
 - c. The Nasonex Multi-Use Savings Coupon specifically provides that it does not apply to Medicare or Medicaid patients or to residents of Massachusetts.
- 76. Merck's website outlines the Terms and Conditions governing the use of the Nasonex Multi-Use Savings Coupon. As is set forth in Paragraph 74 above, these Terms and Conditions expressly exclude Medicare or Medicaid patients and certain residents of Massachusetts:

http://www.nasonex.com/nasx/special-offers.action?link=personalizedProgram&web_program_id=00400000 (last visited Mar. 28, 2012).

d. The Nasonex Savings Multi-Use Savings Coupon functions as an unlawful form of secondary health insurance.

- 77. The fine print accompanying the Nasonex Multi-Use Savings Coupon states: "This coupon is not insurance." The very same fine print, however, instructs pharmacists to process the coupon just like any other form of secondary health insurance coverage:
 - Submit transaction to McKesson Corporation using BIN No. 610524.
 - If primary coverage exists, input coupon information as a secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response. For-cash paying patients, Pharmacist agrees to charge no more than the usual and customary retail price.
- 78. Despite Merck's disclaimer, the Nasonex Multi-Use Savings Coupon functions and is processed just like any other form of secondary health insurance.

e. Merck knows that third party payors cannot tell when a co-pay is subsidized.

- 79. Merck knows that the Nasonex co-pay subsidy program that Merck and its co-pay savings coupon administrator have designed makes it impossible for third party payors to tell if their participants' co-pays are being subsidized by co-pay coupons. Merck admits as much in the fine print that accompanies the coupon, where it attempts to push onto pharmacists the responsibility for making such disclosures: "You agree to notify the patient's insurance carrier the coupon redemption, as may be required by the Terms and Conditions of your relationship with the insurance carrier."
- 80. A similarly ineffectual disclaimer directed at the patient is buried in the fine print of the "Terms and Conditions" section of the Nasonex Multi-Use Savings Coupon: "Patient, guardian, pharmacist, and prescriber agree not to seek reimbursement for all or any part of the benefit received by the patient through this offer. Patient or guardian is responsible for reporting

receipt of coupon benefit to any insurer, health plan, or other third party who pays for or reimburses any of the prescription filled using this coupon, as may be required."

- 3. Merck's Vytorin Multi-Use Savings Coupon
 - a. Merck faced competition from less expensive therapeutic alternatives to Vytorin.
- 81. On July 23, 2004, the FDA approved Vytorin (ezetimibe and simvastatin) as a cholesterol-lowering medicine. Vytorin combines two of Merck's other cholesterol-lowering drugs: Zetia (cholesterol absorption inhibitor) and Zocor (a statin), Generic Zocor has been available since 2006.
- 82. AB-rated equivalents to Vytorin will not come to market until at least 2014. Less expensive therapeutic alternatives to Vytorin include pravastatin (Pravachol) and simvastatin (Zocor).
 - 83. In 2010, U.S. sales of Vytorin were close to \$1 billion.
 - b. In the wake of substitution competition from less expensive therapeutic alternatives, Merck created the Vytorin Multi-Use Savings Coupon
- 84. To combat the substitution competition it was facing from less expensive therapeutic alternatives, in or around 2010, Merck created the Vytorin Multi-Use Savings Coupon:

Eligible patients may

Save Up to \$20 on Each of Up to

12 Qualifying Prescriptions for VYTORIN.

Eligible patients may Save Up to \$20 on Each of Up to 12 Qualifying Prescriptions for VYTORIN.

If eligible, just follow these 3 simple steps to print your coupon to save up to \$20 on each of up to 12 qualifying prescriptions for VYTORIN:

- 1. Talk to your doctor about whether VYTORIN is right for you. You'll need a valid signed prescription and a coupon to redeem the offer.
- 2. Review eligibility restrictions. If eligible, click on the Get Your Coupon link and print the offer from the new window. (Note: If you have a pop-up blocker enabled, please disable it to get your coupon.)
- 3. Take your prescription and coupon to a participating eligible retail or mail-order pharmacy to save up to \$20 on each of up to 12 qualifying prescriptions for VYTORIN. Certain restrictions apply. Please see Terms and Conditions.

The coupon is not insurance.

Eligibility Restrictions Apply.

The coupon is valid for patients with private insurance or cash-paying patients. Not valid for patients covered under Medicaid, Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program.

The coupon is void for Massachusetts residents if a third-party payer reimburses or pays any amount of the prescription price or otherwise provides coverage for VYTORIN.

The coupon can be used only by eligible United States or Commonwealth of Puerto Rico residents at participating eligible retail or mail-order pharmacies in the United States or the Commonwealth of Puerto Rico. Product must originate in the United States or the Commonwealth of Puerto Rico.

The offer is subject to certain terms and conditions. <u>See full Terms and Conditions</u> on coupon.

Please Note: The same coupon offer is available in different forms. For example, you may receive the coupon from your doctor or you may print the coupon yourself from the product Web site. Regardless of how many coupons you receive or print, you may only use the coupons and receive up to \$20 off an eligible prescription, up to 12 times before the expiration date printed on the coupon.

85. The Vytorin Multi-Use Savings Coupon is not a need-based program. It is open to all patients with a prescription for Vytorin, and it subsidizes the co-pays of any privately covered

patients. Patients can print the Multi-Use Savings Coupon directly from Merck's website²³ without providing any identifying information.

- c. The Vytorin Multi-Use Savings Coupon specifically provides that it does not apply to Medicare or Medicaid patients or to residents of Massachusetts.
- 86. Merck's website outlines the Terms and Conditions governing the Vytorin Multi-Use Savings Coupon. As is set forth in Paragraph 84, these Terms and Conditions expressly exclude Medicare or Medicaid patients and certain residents of Massachusetts:
 - d. The Vytorin Multi-Use Savings Coupon functions as an unlawful form of secondary health insurance.
- 87. Although the fine print on the Vytorin Multi-Use Savings Coupon states, "[t]his coupon is not insurance," the same fine print instructs pharmacists to process the card just like any other form of secondary health insurance:
 - Submit transaction to McKesson Corporation using BIN No. 610524.
 - If primary coverage exists, input coupon information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response. For cash-paying patients, Pharmacist agrees to charge no more than the usual and customary retail price.
 - For all other prescriptions, please use the patient's primary method of payment and a new Rx number. Please clear COB secondary screen after processing transaction.
 - e. Merck knows that third party payors cannot tell when a co-pay is subsidized.
- 88. Merck knows that the Vytorin co-pay subsidy program that Merck and its co-pay savings coupon administrator have designed makes it impossible for third party payors to tell if their participants' co-pays are being subsidized by co-pay savings coupons. Merck admits as much in the fine print that accompanies the coupon, where it attempts to push onto pharmacists

http://www.vytorin.com/

the responsibility for making such disclosures: "You agree to notify the patient's insurance carrier of this coupon redemption, as may be required by the Terms and Conditions of your relationship with the insurance carrier."

- 89. A similarly ineffectual disclaimer directed at the patient is buried in the fine print of the "Terms and Conditions" section of the Vytorin Savings Card: "Patient, pharmacist, and prescriber agree not to seek reimbursement for all or any part of the benefit received by the patient through this offer. Patient is responsible for reporting receipt of coupon benefit to any insurer, health plan, or other third party who pays for or reimburses any of the prescription fill using this coupon, as may be required."
- 90. By burying disclosures like these in a sea of fine print, Merck makes a weak attempt to shield itself from liability with instructions it knows and intends will not be seen or followed.

4. Merck's Zetia Multi-Use Savings Coupon

- a. Merck faced competition from less expensive therapeutic alternatives to Zetia.
- 91. On October 25, 2002, the FDA approved Zetia (ezetimibe) as a cholesterol-lowering medicine.
- 92. AB-rated equivalents to Zetia will not be available until at least 2014. Less expensive therapeutic alternatives to Zetia include pravastatin (Pravachol) and simvastatin (Zocor).
 - 93. In 2010, U.S. sales of Zetia were close to \$1 billion.

- b. In the wake of substitution competition from less expensive therapeutic alternatives, Merck created the Zetia Multi-Use Savings Coupon.
- 94. To combat the substitution competition it was facing from less expensive therapeutic alternatives, in or around May 2011, Merck created the Zetia Multi-Use Savings Coupon:



Eligible patients can take advantage of the special offers below.

Try ZETIA FREE for 30 days.

Certain restrictions apply.

Please see Terms and Conditions.

FREE TRIAL OFFER

Get up to \$20 off on each of up to 12 qualifying prescriptions for ZETIA.

Certain restrictions apply. Please see

Terms and Conditions.

Are you eligible?

Certain restrictions apply.

Please see Terms and Conditions.

GET YOUR SAVINGS COUPON

Eligible patients may Save Up to \$20 on Each of Up to 12 Qualifying Prescriptions for ZETIA.

If eligible, just follow these 3 simple steps to print your coupon to save up to \$20 on each of up to 12 qualifying prescriptions for ZETIA:

1. Talk to your doctor about whether ZETIA is right for you. You'll need a valid signed prescription and a coupon to redeem the offer.

- 2. Review eligibility restrictions. If eligible, click on the Get Your Savings Coupon link and print the offer from the new window. (Note: If you have a pop-up blocker enabled, please disable it to get your coupon.)
- 3. Take your prescription and coupon to a participating eligible retail or mail-order pharmacy to save up to \$20 on each of up to 12 qualifying prescriptions for ZETIA. Certain restrictions apply. Please see <u>Terms and Conditions</u>.

The coupon is not insurance.

Eligibility Restrictions Apply.

The coupon is valid for patients with private insurance or cash-paying patients. Not valid for patients covered under Medicaid, Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program.

The coupon is void for Massachusetts residents if a third-party payer reimburses or pays any amount of the prescription price or otherwise provides coverage for ZETIA.

The coupon can be used only by eligible United States or Commonwealth of Puerto Rico residents at participating eligible retail or mail-order pharmacies in the United States or the Commonwealth of Puerto Rico. Product must originate in the United States or the Commonwealth of Puerto Rico.

This offer is subject to certain terms and conditions. See full <u>Terms and Conditions</u> on coupon.

Please Note: The same coupon offer is available in different forms. For example, you may receive the coupon from your doctor or you may print the coupon yourself from the product Web site. Regardless of how many coupons you receive or print, you may only use the coupons and receive up to \$20 off an eligible prescription, up to 12 times before the expiration date printed on the coupon.

95. Merck currently offers a Multi-Use Savings Coupon that pays up to \$20 of a patient's co-pay for up to twelve qualifying prescriptions. The offer, which was previously set expire December 31, 2012, is now set to expire December 31, 2013.²⁴

In addition, patients can receive a free thirty-day trial supply of Zetia through May 31, 2012. No personal information is necessary to print the free trial offer online.

- 96. The Zetia Multi-Use Savings Coupon is not a need-based program. It is open to all patients with a prescription for Zetia, and it subsidizes the co-pays of any privately covered patients. Patients can print the Multi-Use Savings Coupon directly from Merck's website²⁵ without providing any identifying information.
 - c. The Zetia Multi-Use Savings Coupon specifically provides that it does not apply to Medicare or Medicaid patients or to residents of Massachusetts.
- 97. Merck's website outlines the Terms and Conditions governing the use of the Zetia Multi-Use Savings Coupon. As is set forth in Paragraph 94 above, Medicare or Medicaid patients and certain residents of Massachusetts are expressly excluded.
 - d. The Zetia Multi-Use Savings Coupon functions as an unlawful form secondary health insurance.
- 98. Although the fine print on the Zetia Multi-Use Savings Coupon states, "[t]his coupon is not insurance," the same fine print instructs pharmacists to process the card just like any other form of secondary health insurance:
 - Submit transaction to McKesson Corporation using BIN No. 610524.
 - If primary coverage exists, input coupon information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response. For cash-paying patients, Pharmacist agrees to charge not more than the usual and customary retail price.
 - For all other prescriptions, please use the patient's primary method of payment and a new Rx number. Please clear COB secondary screen after processing transaction.

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http://www.zetia.com

e. Merck knows that third party payors cannot tell when a co-pay is subsidized.

- 99. Merck knows that the Zetia co-pay subsidy program that Merck and its co-pay savings coupon administrator have designed makes it impossible for third party payors to tell if their participants' co-pays are being subsidized by co-pay savings coupons. Merck admits as much in the fine print that accompanies the card, where it attempts to push onto pharmacists the responsibility for making such disclosures: "You agree to notify the patient's insurance carrier of this coupon redemption, as may be required by the Terms and Conditions of your relationship with the insurance carrier."
- 100. A similarly ineffectual disclaimer directed at the patient is buried in the fine print of the "Terms and Conditions" section of the Zetia Multi-Use Savings Coupon: "Patient, pharmacist, and prescriber agree not to seek reimbursement for all or any part of the benefit received by the patient through this offer. Patient is responsible for reporting receipt of coupon benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using this coupon, as may be required."

G. Defendant Merck hired McKesson to administer its co-pay subsidy programs.

- 101. Merck depends on cooperation from both pharmacies and its program administrator to conduct the co-pay subsidy programs. Defendant compensates both pharmacies and its co-pay benefit administrator for their efforts. Defendant and its administrator process co-pay subsidy claims through a "shadow claims system" that hides the subsidies from health benefit providers.
- 102. For prescription drugs, plan participants present their co-pay cards or coupons along with their health insurance cards (which include the prescription drug plan) at the

pharmacy. An individual's primary health plan is processed first, establishing the plan member's co-pay or coinsurance amount²⁶ and the price of the drug that will be billed to the health benefit provider.

103. The pharmacist then processes the co-pay card or coupon associated with the co-pay subsidy program. The pharmacist enters into the pharmacy computer information on the co-pay card as though it were a form of secondary insurance. The pharmacist notes the amount of the co-pay that will be subsidized by Defendant and conveys that information to a co-pay card program administrator, who reimburses the pharmacy on Defendant's behalf.²⁷ The plan member pays out-of-pocket the difference between his or her co-payment (or co-insurance) and the amount subsidized by Defendant. The pharmacist then charges the health benefit provider the full amount of the health benefit provider's usual payment for the branded drug in question, *i.e.*, the health benefit provider pays an amount for the co-pay subsidy drug's purchase as if the plan member had made full personal payment of his/her cost sharing obligation.

104. During a transaction without the use of the unlawful co-pay subsidy, the pharmacy reports data to the health benefit provider (or its PBM) that enables the provider to know the claim, drug dispensed, amount paid by the plan, amount of co-payment/co-insurance paid, and other data. In a transaction with the use of the subsidy, the information transmitted to the health benefit provider does not include any disclosure that a subsidy was paid. The plan member's cost-sharing obligation is simply reported to the benefit provider as having been paid.

For plan participants with a co-insurance responsibility, pharmacists determine the dollar amount to be paid by the member. Sometimes, this amount is referred to, inaccurately, as a "co-pay."

The administrator pays pharmacies for all co-pay subsidies on the manufacturer's behalf every fourteen to twenty eight days. The manufacturer repays the administrator on a similar schedule.

105. As F. Everett Neville, chief trade relations officer at Express Scripts, one of the country's largest PBMs, told the New York Times in January 2011: "[t]he payer doesn't know, and the P.B.M. doesn't know. . . . We have no ability to stop it and no ability to prohibit it."

106. Here, Defendant hired McKesson to administer its co-pay subsidy programs, thus, act as its agent for the payment of monies to pharmacies from which participants purchase their prescription drugs.

1. McKesson administers the Janumet/Janumet XR/Januvia, Nasonex, Vytorin and Zetia co-pay subsidy programs for Merck.

107. McKesson Corporation, with headquarters at One Post Street in San Francisco, California, administers co-pay subsidy programs for Janumet/Janumet XR/Januvia, Nasonex, Vytorin, and Zetia, all marketed by Merck. McKesson's co-pay program, called LoyaltyScript, "serve[s] more than 17,000 patients every day" and has "saved patients more than \$335 million in out-of-pocket prescription costs." According to McKesson, the LoyaltyScript program allow manufacturers to "[i]ncrease market share through co-pay discounts that capture new customers and "[g]ain valuable insight into program utilization to maximize [their] marketing ROI."

108. McKesson's co-pay subsidy administration program "[s]erve[s] more than 17,000 patients every day" and has "saved patients more than \$335 million in out-of-pocket prescription costs." According to McKesson, the LoyaltyScript program allows manufacturers to [i]ncrease market share through co-pay discounts that capture new customers" and "[g]ain valuable insight into program utilization to maximize [their] marketing ROI." 29

http://sitesanckesson.cornimprs/solutions/loyaltyscript_difference.shtml.

http://sites.mckesson.com/mprs/solutions/loyaltyscript_benefits.shtml.

109. McKesson holds a patent, applied for on March 31, 2006, for a means of processing co-pay subsidies at the point of sale, that is, when the patient brings his prescription to the pharmacy.³⁰ McKesson's patent contemplates electronically receiving claims from pharmacies that are separate and distinct from claims that are submitted to patients' health benefit plans:

What is claimed is: 1. An apparatus comprising: one or more processors configured to receive *an electronic claim transaction* submission at an administrator in response to a purchase transaction of a client at a point of sale of a healthcare provider, a primary payer separate and distinct from the administrator also receiving the electronic claim transaction submission from the healthcare provider to initiate adjudication of a primary claim for *an offset of at least a portion of a cost associated with the purchase transaction*, wherein the one or more processors are configured to adjudicate, in response to receiving the electronic claim transaction submission and separate and distinct from the primary claim, *one or more services of a program of an administrator to which the client is enrolled*, the purchase transaction being applicable to the program, the one or more services including one or more marketing services or interventions, wherein the one or more processors are also configured to trigger provision of the one or more services to the client in response to adjudication of the one or more services.³¹

110. McKesson's patent asserts that the pharmaceutical industry had not previously identified a method of providing cost-saving benefits in light of the variability of co-pays:

[previously,] monetary incentives for prescription fulfillment have been limited to a uniform value for a particular product offer. For insured patients, pharmaceutical marketers have sought the ability to vary the incentives based upon the individual patient's co pay amount, which can vary considerably across prescription benefit plans based upon individual patient coverage, cost sharing tiers, drug formulary design, and plan exclusions. To date, no solutions have been identified to address this variability in patient cost-share amounts on a patient-specific basis in real time using the mail-in rebate, debit card or credit card mechanisms.³²

³⁰ U.S. Patent No. 7,957,983 (issued June 7, 2011).

Id. at Claim 1 (emphasis added).

³² *Id.* at Background of the Invention (emphasis added).

111. The patent goes on to say that McKesson's invention solved the industry's "problem" of not being able to undermine health benefit providers' cost-sharing provisions:

[The [monetary] secondary benefit may offset at least a portion of the out-of-pocket expense for a purchase transaction applicable to the respective program. . . [T]he secondary benefit may be provided in real time at the point of sale . . . by linking secondary benefit with the dispensing and purchase of a medication. The secondary benefit may also be tied to a patient's actual primary benefit, such as by determining the secondary benefit as a percentage of a primary benefit (further offsetting the cost associated with a purchase transaction). ³³

112. McKesson's patent notes that "the adjudications may occur sequentially, such that adjudication at the primary payer occurs prior to adjudication at the administrator," implying that the adjudications *could instead* take place simultaneously or in the opposite order. Yet Figure 4 of the patent (reproduced below) shows two separate feedback loops, one in which the "healthcare provider" (*i.e.* the pharmacy) submits the "primary claim" to the "primary payer" (*i.e.* bills the health benefit plan) and a second in which the "healthcare provider" separately submits a "service request" to the co-pay subsidy administrator. The co-pay subsidy administrator then provides "Backstage Support Services:" confirming that the patient is enrolled in the program, paying the "secondary benefit" (the co-pay subsidy) to the pharmacy, and submitting information about the patient's prescription to the "sponsor" (the drug manufacturer): FIG, 4,

H. Health benefit providers do not know, and cannot know, when Defendant subsidizes their participants' co-pays.

113. Health benefit providers are generally aware that drug companies offer co-pay subsidy programs, but health benefit providers do not know, and cannot know, which of the

Id. at Summary of the Invention.

³⁴ *Id.* at Secondary Benefits Provided by Administrator (emphasis added).

prescriptions that they have paid for have been subsidized. Pharmacists process subsidies as instructed by Defendant and its claims administrator, and they do not tell health benefit providers or PBMs when a prescription has been subsidized. Defendant, however, possesses detailed records of each and every subsidized prescription. The extent of the injury to Fund and the classes can easily be determined through discovery of Defendant's co-pay subsidy program records.

- I. Defendant's co-pay subsidy programs intentionally interfere with the relationship between health benefit providers and their participants.
- 114. By providing undisclosed payments to reduce or eliminate the cost-sharing mechanism in thousands of health plan contracts for widely used maintenance prescription drugs, Defendant unfairly undermines health benefit providers' best attempts to control prescription drug costs. Pharmacy and Therapeutics ("P&T") committees arrive at formulary placement decisions after considerable decision-making, in an effort to address overall prescription drug costs as a burden on the delivery of quality health care. Even small co-pay subsidies meddle with the cost share balance so carefully struck by P&T committees in formulary tier structures and cost containment provisions in prescription drug benefit plans. Defendant offers such sweeping bribes that it often effectively reduces the co-pay for branded drugs to less than the average co-pay for therapeutic or AB-rated generic alternatives, thereby completely neutralizing health benefit providers' contractual tiered formulary structure.
- 115. Defendant intends to interfere with health plans' cost-sharing provisions. For example, McKesson's patent (discussed above) specifically contemplates a co-pay subsidy program that absorbs the entire amount of the patient's cost-share obligation:
 - "[A] program could be designed to capture the patient's cost share requirement for a drug as determined by the patient's prescription drug coverage and subsequently provide the patient an additional discount on the final prescription

cost. . . . Although fixed discounts may be offered, such as a flat \$5.00 discount, other techniques may be used, such as variable discounts which reduce all patient cost share amounts, regardless of individual drug benefit coverage, to a fixed dollar amount."³⁵

116. The co-pay subsidy kickbacks also force other potential short or long-term changes in available prescription drug coverage. Without a means of enabling cost sharing and make no mistake about it, Defendant's co-pay subsidy programs prevent plans and their member from agreeing to effective sharing programs), plans are left to consider wholesale cost shifting, under which the benefit provider pays none of the cost of a branded drug, and the member pays all of the cost, when alternatives to a branded drug exist. At base, Defendant has unfairly, deceptively and improperly interfered with health insurance providers' ability to effectively contract for appropriate cost-sharing provisions in insurance contracts.

CLASS ALLEGATIONS

117. Fund brings this action pursuant to Fed.R.Civ.P. 23, on behalf of itself and four national classes (one for each of the four programs discussed above) defined as:

All entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of a co-pay subsidy drug prescribed to natural persons covered by such contract, policy, or plan, and who paid for at least one prescription for Janumet/Janumet XR/Januvia, Nasonex, Vytorin, and Zetia that was subsidized by Defendant's co-pay subsidy program(s).

- 118. The class periods runs from when Defendant started offering the Janumet/Janume XR/Januvia, Nasonex, Vytorin, and Zetia co-pay subsidy programs until Defendant stops offering the programs. The precise period will be identified through discovery.
- 119. Excluded from the classes are (i) Defendant, Defendant's legal representatives, officers, directors, assignees, predecessors, and successors, (ii) federal and state governmental

³⁵ *Id.* at Detailed Description of the Invention.

entities administering prescription drug programs under Medicare, Medicaid, and or other federally or state-sponsored programs, and (iii) counsel for plaintiff and the classes' self-funded health benefit plans (if any).

- 120. All class members have suffered, and will continue to suffer, harm and damages as a result of Defendant's unlawful and wrongful conduct.
- 121. Defendant's co-pay subsidies are specifically targeted to undermine the cost-shat provisions in those contracts.
- 122. Class members can be precisely determined from Defendant's records, the record of the administrator of Defendant's co-pay subsidy programs, and pharmacy records. Members of the classes themselves are unable to identify the subsidized prescriptions. However, Defendant possesses information about the subsidized prescriptions, including the name and specific identifying information about each participating member and the pharmacy where the prescription was filled. The pharmacy has a record of both the amount of subsidy and the individual's health plan. The administrator also has this information, as well as the accumulated results of the program through all pharmacies. No uninjured parties will be included within the classes because each member can be determined with specificity, based on actual transactional data.
- 123. The fact of injury or damages to each class member can also be reasonably estimated from existing data. Aggregate damages to the classes as a whole can reasonably be estimated from existing data, and commonly used mechanisms by which to allocate that award among class members exist.

- 124. The classes consist of thousands of private health benefit providers. These providers are geographically dispersed throughout the United States. The disposition of all claims in a single action will substantially benefit all parties and the Court.
 - 125. Plaintiff Fund is the proposed representative for each of the classes.
- 126. The claims of Fund are typical of the claims of the classes. Fund purchased drugs on behalf of its participants whose cost-share obligations were subsidized by Defendant. Fund, like all class members, paid for too many co-pay subsidy drug prescriptions as a result of Defendant's subsidies. Fund will fairly and adequately protect all interests of the classes. Fund has retained counsel with substantial experience prosecuting nationwide third party payor class actions. Fund and its counsel are committed to vigorous prosecuting this action on behalf of the classes and have the financial resources necessary to do so.
- 127. The factual and legal issues regarding Defendant's alleged misconduct are common to all class members and represent a common thread of misconduct resulting in injury to Fund and the classes. Common questions of law and fact include:
 - A. Whether Defendant engaged in a course of conduct that improperly increased plaintiff's and other class members' drug costs;
 - B. Whether Defendant's co-pay subsidy plan induced subscribers of Plaintiff's and other class members health plans to breach their obligations to pay the portion of prescription costs required by their respective plans;
 - C. Whether Defendant engaged in kickback schemes to increase plaintiff's and other class members' drug costs;
 - D. Whether Plaintiff and the other members of the classes were injured by the conduct of Defendant and, if so, the appropriate class-wide measure of damages; and
 - E. Whether Plaintiff and the other members of the classes are entitled to injunctive relief.

128. Prosecution of separate actions by individual class members would create the risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for Defendant.

129. Defendant has acted on grounds generally applicable to all class members in that Defendant's unlawful actions uniformly impacted all class members. Accordingly, injunctive relief is necessary to protect all class members from further injury.

130. Plaintiff knows of no difficulty that would prevent this case from being maintained as a class action. A class action is the superior method for fairly and efficiently adjudicating this controversy. The cost of litigating a single action would prevent most class members from bringing suit individually.

131. Class action treatment will, among other things, allow a large number of similarly situated entities to prosecute their common claims in a single forum thus avoiding the unnecessary duplication of resources that numerous individual actions would require. Moreover, class action treatment allows injured payors, including smaller plans with limited means, to seek redress on claims that might be impracticable to pursue individually. Thus, absent a class action, there would be no remedy at law for thousands of injured entities. Absent a class action, there would be no mechanism for imposing uniform equitable injunctive relief to the classes as a whole.

<u>COUNT ONE</u> (Tortious Interference With Contractual Relations)

- 132. Plaintiff repeats the allegations contained in Paragraphs 1-131 as if fully set forth herein.
- 133. The Fund's health plan with its participants, and the terms of other class members' health plans, constitutes a contract between the health plan and its beneficiaries as to

the terms and conditions under which the Fund and other class members will pay for health services, including prescription drugs, for their respective beneficiaries.

- as to the amount the beneficiaries must pay toward the purchase of prescription drugs, the terms of the plans are substantially similar in that they require beneficiaries to pay a lower co-pay amount for lower-cost generic drugs and pay a higher co-pay for higher-cost branded drugs such as those covered by Defendant's co-pay subsidy plan.
- 135. The purpose of these differential co-pay obligations under the respective health plans is the same, to encourage the beneficiary to purchase generic drugs, which causes the health plans to incur a significantly lower cost than for the payment of Defendant's brand-name drug.
- 136. Defendant is aware of the obligation of health plan beneficiaries to pay a higher co-pay for its branded prescription drugs than for equivalent generic prescription drugs.
- 137. The purpose of Defendant's co-pay subsidy plan is to defeat that obligation by making its branded prescription drugs available to health plan beneficiaries at the same out-of-pocket cost to the beneficiary as equivalent generic prescription drugs.
- 138. Defendant's co-pay subsidy plan induces beneficiaries of the Fund and other class members' health plans to breach their obligation under their respective health plans to pay the full amount of the required co-pays for prescription drugs.
- 139. As a result of Defendant's inducing beneficiaries of the Fund and other class members' health plans to breach those obligations, the Fund and other class members have been damaged because they have incurred the cost of paying for higher-cost branded drugs covered by Defendant's prescription subsidy plan, rather than lower-cost generic drugs which plan

beneficiaries would have otherwise purchased, but for Defendant's prescription subsidy plan making Defendants' branded drugs have the same out-of-pocket expense to plan beneficiaries as equivalent generic drugs.

- 140. Defendants are aware of the existence of the contractual relationship between the Fund and other class members on the one hand and their respective participants on the other hand because, in order to obtain a coupon for Defendant's co-pay subsidy program, the beneficiary must advise Defendant that the beneficiary is covered by a private health insurance plan.
- 141. Defendant is aware of the specific contractual relationship between the Fund and other class members on the one hand and their respective beneficiaries on the other hand no later than the first time a coupon is used during the process of processing claims made under the copay subsidy program. All of Defendant's co-pay subsidy coupons are usable for multiple purchases of Defendant's branded prescription drugs.
- 142. As a result of the foregoing, the Fund and other class members have been damaged in that they had to incur greater expenses for Defendant's branded prescription drugs than it otherwise would have incurred but for beneficiaries using Defendant's co-pay subsidy plan.

WHEREFORE, Plaintiff Fund, on behalf of itself and the proposed classes, respectfully requests that the Court:

- A. Determine that this action may be maintained as a class action pursuant to Fed. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the classes, and declare plaintiff Fund the class representative for each of the classes;
- B. Enter judgment against Defendant in favor of Fund and the classes for damages;
- C. Award plaintiff and the classes their costs of suit, including reasonable attorneys fees as provided by law;
- D. Enjoin Defendant from offering these or similar co-pay subsidy programs; and

E. Grant such other relief as the Court may deem just.

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C. Attorneys for Plaintiff

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: April , 2012

DEMAND FOR JURY TRIAL

The undersigned hereby demand a trial by jury for all issues so triable.

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C. Attorneys for Plaintiff

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: April , 2012